# **Complete Summary**

#### **GUIDELINE TITLE**

Clinical implications of obesity with specific focus on cardiovascular disease: a statement for professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism.

# **BIBLIOGRAPHIC SOURCE(S)**

Klein S, Burke LE, Bray GA, Blair S, Allison DB, Pi-Sunyer X, Hong Y, Eckel RH. Clinical implications of obesity with specific focus on cardiovascular disease: a statement for professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism: endorsed by the American College of Cardiology. Circulation 2004 Nov 2;110(18):2952-67. [213 references] PubMed

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **COMPLETE SUMMARY CONTENT**

SCOPE

 $\label{eq:methodology} \mbox{METHODOLOGY - including Rating Scheme and Cost Analysis} \\ \mbox{RECOMMENDATIONS}$ 

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## SCOPE

## **DISEASE/CONDITION(S)**

- Cardiovascular disease (CVD)
- Obesity

# **GUIDELINE CATEGORY**

Management Prevention Treatment

## **CLINICAL SPECIALTY**

Cardiology
Family Practice
Internal Medicine
Nursing
Physical Medicine and Rehabilitation
Preventive Medicine

## **INTENDED USERS**

Health Care Providers Physicians

## **GUIDELINE OBJECTIVE(S)**

To review the physiological and cardiovascular effects of weight loss and provide clinicians with appropriate treatment guidelines for weight management in patients with obesity and cardiovascular disease

#### TARGET POPULATION

Patients with obesity and cardiovascular disease (CVD) or who have coronary heart disease (CHD) risk factors

## INTERVENTIONS AND PRACTICES CONSIDERED

## **Evaluation**

- 1. Obtain patient history: standard medical interview, weight history, dietary history, assessment of physical activity and function, obesity-related health risks, assessment of possible psychiatric illnesses (including binge eating and depression), and assessment of ability and desire to lose weight)
- 2. Physical examination
  - Body mass index (BMI)
  - Waist circumference
  - Blood pressure
  - Assessment for physical signs of cardiac abnormalities (i.e., right or left ventricular dysfunction, congestive heart failure, and pulmonary disease)
- 3. Laboratory tests
  - Electrocardiogram (ECG)
  - Standard blood tests to search for coronary heart disease (CHD) risk factors including:
    - Fasting blood glucose and glucose tolerance test (prediabetes)
    - Low density lipoprotein cholesterol (LDL-C), and high density lipoprotein cholesterol (HDL-C), and triglycerides (dyslipidemia)
  - Sleep studies
  - Exercise treadmill test
  - · Electron beam computerized tomography scanning

## Management/Treatment

- 1. Dietary interventions
  - Very-low-calorie diets (VLCDs)
  - Low-calorie diets (LCDs)
  - Low-fat diet
  - Low-carbohydrate diets
  - Use of low-energy-density foods
- 2. Physical activity (>30 minutes of at least moderate-intensity physical activity on most but preferably all days of the week)
- 3. Behavioral therapy including self-monitoring (food diaries, physical activity logs, weight scales) and formal behavioral therapy
- 4. Pharmacotherapy
  - Sibutramine
  - Orlistat
  - Phentermine
  - Dietary supplements and herbal products including chromium picolinate, garcinia cambogia (source of hydroxycitrate), chitosan, phenylephrine from *Citrus aurantium* (bitter orange), ma huang (source of ephedra\* alkaloids) with or without guarana (source of caffeine)
- 5. Bariatric surgery
  - Gastric banding
  - Gastroplasty
  - Gastric bypass
  - Biliopancreatic diversion with or without duodenal switch

\*Note: The sale of ephedra in over-the-counter products was recently banned by the Food and Drug Administration (FDA) because of concerns about serious cardiovascular effects.

## **MAJOR OUTCOMES CONSIDERED**

- Obesity-related risk factors for coronary heart disease (CHD) including:
  - Insulin resistance and type 2 diabetes mellitus
  - Dyslipidemia
  - Hypertension
  - Inflammation
  - Autonomic nervous system dysfunction
  - Pulmonary disease
- Cardiovascular disease events or mortality
- Weight loss
- Cardiovascular structure and function

## **METHODOLOGY**

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

# **METHOD OF GUIDELINE VALIDATION**

Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on August 18, 2004, and was endorsed by the American College of Cardiology Foundation.

## **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

#### **Treatment Guidelines**

The goal of weight loss therapy for patients with cardiovascular disease (CVD) is to reduce or eliminate coronary heart disease (CHD) risk factors and improve cardiac function. Aggressive weight loss therapy could be harmful in selected patients, such as those who have had a recent myocardial infarction or stroke or who have unstable angina, and attempts at weight loss should be delayed until these patients are medically stable.

## **Clinical Evaluation**

The physician's office should be an environment that is sensitive to the needs of obese patients. The waiting room should contain chairs without arms, large gowns and large blood pressure cuffs should be available, and a scale that can weigh patients who weigh >300 lb should be available and located in a private area. The initial assessment should include an appropriate history, physical examination, and laboratory tests.

## **History**

In addition to a standard medical interview, a patient's history should include an assessment of (1) weight history (highest and lowest adult body weight, previous weight loss attempts, weight pattern, and potential triggers and social and environmental factors that contributed to weight gain), (2) dietary history, including an assessment of types and timing of meals and snacks and an attempt to identify possible triggers that result in excessive energy intake, (3) physical activity and function (daily and exercise activities, physical limitations, effect of obesity on physical lifestyle), (4) obesity-related health risk (age of onset and duration of obesity, family history of obesity and obesity-related medical complications, current obesity-related disease), (5) possible psychiatric illnesses, such as binge eating disorder and depression, that may require therapy before a weight loss program is initiated, and (6) ability to lose weight (desire to lose weight, weight loss goals and expectations, limitations for achieving weight loss, including medications and illnesses, lifestyle and work patterns, financial resources, and special needs).

## **Physical Examination**

The patient's body-mass index (BMI) and waist circumference should be determined. BMI is generally correlated with percentage of body fat in a curvilinear fashion. Some people with an "obese" BMI, who have a normal amount of body fat and a large muscle mass, are not at increased risk for CHD, whereas people with a "normal" BMI, who have excessive body fat and small muscle mass, are at increased risk. Waist circumference, measured halfway between the last rib and the iliac crest, correlates with abdominal fat mass. The table below titled "Weight Classification by BMI" provides a classification of risk based on BMI. A waist circumference of  $\geq 88$  cm (35 in) for women and  $\geq 102$  cm (40 in) for men is

associated with an increased risk of metabolic diseases and CHD. Additional assessments should include measuring blood pressure with a large cuff and searching for physical signs of right or left ventricular dysfunction, congestive heart failure, and pulmonary disease. An electronic stethoscope can increase a physician's ability to detect cardiac abnormalities in patients who are extremely obese.

Table: Weight Classification by BMI\*

	<b>Obesity Class</b>	BMI kg/m²	Disease Risk
Underweight		<18.5	Increased
Normal		18.5-24.9	Normal
Overweight		25.0-29.9	Increased
Obesity	I	30.0-34.9	High
	II	35.0-39.9	Very high
Extreme Obesity	III	<u>&gt;</u> 40.0	Extremely high

<sup>\*</sup> Data from Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults -- The Evidence Report. National Institutes of Health. Obes Res. 1998;6:51S-209S.

Additional adiposity-related risk factors: waist circumference >40 (in men) and >35 (in women); weight gain of  $\geq$ 5 kg since age 18-20 years.

## **Laboratory Tests**

An electrocardiogram (ECG) is needed to check for evidence of CHD and to obtain a baseline tracing for future comparisons. Standard blood tests should be performed to search for CHD risk factors, including prediabetes (impaired fasting blood glucose or impaired glucose tolerance), dyslipidemia (increased triglycerides, low high density lipoprotein cholesterol [HDL-C], and increased low density lipoprotein cholesterol [LDL-C]), and the metabolic syndrome. Additional studies may be needed to further evaluate specific clinical suspicions based on the history and physical examination, such as sleep studies to diagnose obesity hypoventilation syndrome (OHS) or obstructive sleep apnea (OSA) and an exercise treadmill test or electron beam computerized tomography scanning or both to evaluate CHD risk. The comparative value of exercise tolerance testing and electron beam computerized tomography in obese subjects has not been determined. Exercise treadmill testing is not recommended for patients without cardiac symptoms, and neither exercise treadmill testing nor electron beam computerized tomography scanning should be performed in patients who are at low risk for CHD, based on clinical judgment or Framingham risk score.

## **Therapeutic Options**

Appropriate management requires identifying patients who need treatment, developing a realistic treatment plan, and implementing a defined treatment strategy that can be modified as needed during long-term surveillance. The Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults was developed by the North American Association for the Study of Obesity in conjunction with the National Heart, Lung, and Blood Institute. Suggested guidelines from the guide for selecting among different weight loss

treatment options, based on disease risk, are shown in the table below titled "Weight Loss Treatment Guidelines." A typical clinical consultation involves a physician's giving advice without adequate consideration of the patient's priorities, motivation, or confidence in undertaking change. In contrast, obesity therapy should involve "patient-centered counseling," which encourages patients to set goals and express their own ideas for therapy, with input from the healthcare professional. The treatment plan also must take into account the patient's readiness for therapy and the patient's ability to comply with the proposed treatment plan. Realistic goals should be established and frequent follow-up visits should be scheduled to monitor progress, modify the treatment plan as needed, and provide encouragement. Effective therapy requires a long-term structured approach with continued support from the physician and other caregivers, particularly during periods of patient recidivism and weight regain.

Reducing energy intake is the cornerstone of weight management therapy. Providing appropriate nutrition counseling and the behavior modification therapy needed to implement dietary changes within the setting of a busy outpatient practice is difficult if not impossible for most physicians because they do not have the time or expertise to provide this kind of care. Therefore, referral to a reputable weight loss program or experienced dietitian should be considered, if these resources are available. Additional therapy with weight loss medications or bariatric surgery can be useful in properly selected patients.

Table: Weight Loss Treatment Guidelines\*

BMI Category, kg/m²					
Treatment	25.0- 26.9	27.0-29.9	30.0- 34.9	35.0-39.9	<u>&gt;</u> 40.0
Diet, physical activity, behavior therapy, or all 3	Yes	Yes	Yes	Yes	Yes
Pharmacotherapy**		With obesity- related disease	Yes	Yes	Yes
Surgery***				With obesity- related disease	Yes

<sup>\*</sup> Data from Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults -- The Evidence Report. National Institutes of Health. Obes Res. 1998;6:51S-209S.

# **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

<sup>\*\*</sup> Pharmacotherapy should be considered only in patients who are not able to achieve adequate weight loss by available conventional lifestyle modifications and who have no absolute contraindications for drug therapy.

<sup>\*\*\*</sup> Bariatric surgery should be considered only in patients who are unable to lose weight with available conventional therapy and who have no absolute contraindications for surgery.

The type of evidence supporting each recommendation is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Weight loss in obese patients can improve or prevent many of the obesity-related risk factors for coronary heart disease (CHD) (i.e., insulin resistance and type 2 diabetes mellitus, dyslipidemia, hypertension, and inflammation) and can improve diastolic function.

#### **POTENTIAL HARMS**

- The most common side effects of *sibutramine* are dry mouth, constipation, and insomnia. Sibutramine increases heart rate (a dose of 10 to 15 mg/d causes an increase in heart rate of 4 to 6 bpm) usually in the first few weeks of treatment and lasts as long as the drug is taken. Sibutramine also causes a dose-related increase in blood pressure (a dose of 10 to 15 mg/d causes an average increase in systolic and diastolic blood pressure of 2 to 4 mm Hg) and can prevent weight loss-induced decrease in blood pressure.
- About 70% to 80% of subjects treated with orlistat experienced ≥1 gastrointestinal event as compared with approximately 50 to 60% of those treated with placebo. Gastrointestinal events usually occurred early (within the first 4 weeks), were of mild or moderate intensity, were usually limited to 1 or 2 episodes, and resolved despite continued orlistat treatment. Approximately 4% of subjects treated with orlistat and 1% of subjects treated with placebo withdrew from the studies because of gastrointestinal complaints. During treatment, small decreases in plasma fat-soluble vitamins, particularly vitamins A, D, and E, can occur, although plasma concentrations almost always remain within the reference range. A few patients, however, may experience decreases in plasma vitamin concentrations to below the reference range.
- Orlistat can have medically significant effects on the absorption of lipophilic medications if both drugs are taken simultaneously. Subtherapeutic plasma cyclosporine levels that occurred in organ transplant recipients after they began orlistat therapy for obesity have been reported.
- The most common side effects of *phentermine* are dry mouth, insomnia, and constipation. Although all sympathomimetic agents can increase blood pressure and heart rate, these side effects are uncommon when weight loss is adequate.
- The perioperative mortality rate within 30 days after *open bariatric surgery* is approximately 1% but can vary depending on the experience of the surgeon. Approximately 75% of deaths are caused by anastomotic leaks and peritonitis and 25% by pulmonary embolism. *Laparoscopic gastric bypass* is associated with fewer wound complications, less postoperative pain, less blood loss, and shorter hospital stays and convalescence periods than the open procedure; however, late anastomotic strictures occur more frequently after the laparoscopic than after the open procedure.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Living with Illness Staying Healthy

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

Klein S, Burke LE, Bray GA, Blair S, Allison DB, Pi-Sunyer X, Hong Y, Eckel RH. Clinical implications of obesity with specific focus on cardiovascular disease: a statement for professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism: endorsed by the American College of Cardiology. Circulation 2004 Nov 2;110(18):2952-67. [213 references] PubMed

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2004 Nov 2

## **GUIDELINE DEVELOPER(S)**

American Heart Association - Professional Association

## **SOURCE(S) OF FUNDING**

American Heart Association

## **GUIDELINE COMMITTEE**

Working Groups of the American Heart Association

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Council Members: Samuel Klein, MD; Lora E. Burke, RN, MPH, PhD; George A. Bray, MD; Steven Blair, PED; David B. Allison, PhD; Xavier Pi-Sunyer, MD; Yuling Hong, MD, PhD; Robert H. Eckel, MD

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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Writing Group Member Name	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant/Advisory Board	Other
Dr. Samuel Klein	Transneuronix	Merck	None	Obesity and Diabetes Educational Council (Roche); Enteromedics	None
Dr. Lora E. Burke	None	None	None	None	None
Dr. George Bray	None	None	None	Takeda Pharmaceutical; Johnson & Johnson	None
Dr. Steven N. Blair	Abbott Laboratories; Human Kinetics; McNeil Consumer & Specialty Pharmaceuticals, Inc; Masterfoods; WESTAT			Life Fitness International; Jenny Craig; Bally Total Fitness Sports Medicine; Sherbrooke Capital; Miavita; International Life Sciences Institute Center for Health Promotion; Healthetech; Westport Realty; Ruder Finn	None
Dr. David B. Allison	Alabama Agricultural Land Grant Alliance; Coca-Cola; General Mills;	American Oil Chemists Society; Bristol Myers Squibb/Mead	None	Air Canada; Archer Daniels Midland; Coca-Cola; Cytodyne Technologies Inc;	Current Drugs Ltd; Elsevier; Marcell

Writing Group Member Name	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant/Advisory Board	Other
	Gerber Foundation; International Life Sciences Institute; Janssen-Cilag; Johnson & Johnson; M&M Mars; Merck; National Alliance for Research on Schizophrenia and Affective Disorders; NIH; NSF; Ortho- McNeil Pharmaceuticals; Pfizer Central Research; Proctor & Gamble; SlimFast Foods Company	Societies of Experimental Biology; Health Learning Systems; Institute for the Future		Entelos; FTC; Fertin Pharma A/S; FDA; Genome Explorations; Gibson, Dunn & Crutcher LLP; International Food Information Council; Kraft Foods; Ligand Pharmaceuticals; Lily Research Labs; Lockheed Martin; Maynard, Cooper & Gale, LLP; McKenna & Duneo, LLP; Nutricia; NutriPharma; Parenti, Falk, Waas, Hernandez & Cortina; Paterson, MacDougall; Pinnacle; Rand Corporation; Research Testing Laboratories; Rexall; RW Johnson Pharmaceutical Research Institute; United Soybean Board; United States Postal Service; Veterans Administration; Wilentz, Goldman & Spitzer	Decker Publishing
Dr. Pi- Sunyer	Novartis; Merck; Johnson & Johnson	None	None	Sanofi Synthelabo; Transneuronix; McNeil Specialty Products; Roche; Lilly	None
Dr. Yuling Hong	None	None	None	None	None
Dr. Robert Eckel	Merck	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit.

## **ENDORSER(S)**

American College of Cardiology Foundation - Medical Specialty Society

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the American Heart Association Web site.

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

#### **NGC STATUS**

This NGC summary was completed by ECRI on January 19, 2005. The information was verified by the guideline developer on February 23, 2005.

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